REMARKS

In part 12 of the Office Action Summary, none of the boxes are checked. However, the applicant filed a certified copy of the priority document on April 10, 2007, together with a priority claim. The PAIR system shows that the priority document was received. Applicant (Eiji NOGAMI) respectfully requests that the next communication from the Patent Office kindly acknowledge receipt of the claim for priority under 35 U.S.C. §119 and receipt of the certified copy of the priority document.

The foregoing amendments amended the beginning of the present specification disclosure to identify prior applications. Claims 1 and 13 were amended in the foregoing amendments to define that the drug of the drug-containing layer is released in a digestive system. This aspect of applicant's invention is described on page 14, line 24 to page 15, line 5; page 35, line 9 *et seq.* and elsewhere in the present specification disclosure. The Official action mailed on August 1, 2007 withdrew claims 11 and 12 as directed to a non-elected invention. Accordingly, claims 1-10 and 13 are pending in the application for consideration by the examiner. Applicant respectfully requests reconsideration and allowance of these claims for at least the following reasons.

Claims 1-10 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,456,745 of Roreger *et al.* (Roreger). This rejection is set forth on page 2 of the Official action. Applicant respectfully submits that the inventions defined in claims 1-10 and 13 are patently distinguishable from the teachings of Roreger within the meaning of 35 U.S.C. §102 or 35 U.S.C. §103 for at least the following reasons.

The teachings of Roreger do not contemplate or suggest, *inter alia*, an orally administered agent free of a bioadhesive layer, comprising a drug-containing layer and a water-swellable gel-forming layer, the water-swellable gel-forming layer being provided as an

outermost layer of said orally administered agent, *and the drug of the drug-containing layer being released in a digestive tract*, as required in present claims 1 and 13. Accordingly, applicant respectfully submits that the teachings of Roreger cannot contemplate or suggest the inventions defined in claims 1 and 13, as well as the inventions in claims 2-10 that depend on claim 1.

For example, the teachings of Roreger, at best, propose:

- the gel film being produced of components having optimum skin and mucous membrane tolerance (column 2, lines 15-17),
- In a preferred embodiment, the substrate with which the gel film interacts is damaged skin (column 6, lines 60-61),
- In another preferred embodiment, the substrate with which the gel film interacts is intact skin (column 7, lines 61-62),
- By this way of alternating release of active substances, it is possible, e.g. to consider more purposeful specific therapy schemes, which is usual in the peroral application of medicines, but without the disadavantages of peroral medicines (column 9, line 65 - column 10, line 2), and
- According to a further preferred embodiment, the substrate with which the gel film interacts is mucous membrane (column 10, lines 29-30).

From the above, it is readily apparent that the teachings of Roreger are concerned with a flexible, hydrophilic gel film that is applied to the skin or mucous membrane, not an orally administered agent containing a drug that is released in the digestive tract, as required in present claims 1 and 13. While the Official action stated that the presently claimed orally administered agent is "intended use" and not considered a patentable limitation during prosecution of composition claims before the USPTO, applicant respectfully submits that this position is not

correct for the present claims. The presently claimed invention is directed to solving problems unique to an orally administered agent containing a drug. It is well established in the case law that if limitations in the preamble of a claim necessarily give meaning to the claim and properly define the invention, then such limitations must be considered when determining the patentability of the claims. The predecessor court of the Court of Appeals for the Federal Circuit (CAFC), namely, the Court of Custom and Patent Appeals (CCPA) summarized this approach in *Kropa v. Robie*, 88 USPQ 478 (1951), after reviewing some 37 cases that turned on the limiting nature of the preambles to the claims in suit. See also *Loctite Corp. v. Ultraseal Ltd.*, 228 USPQ 90, 94 (Fed. Cir. 1985). According to the court in *Kropa*:

> [T]he preamble has been denied the effect of a limitation where... the claim or [interference] count apart from the introductory clause completely defined the subject matter [of the invention], and the preamble merely stated a purpose or intended use of that subject matter. On the other hand, in those... cases where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims or counts.

Examples of preambles cited in *Kropa* as expressly or impliedly held to express a limitation in the claims are "An insecticide" and "An insecticide composition." Applicant respectfully submits that the claims in this application present precisely the situation where the preamble of a claim has been held to express a limitation in the claim in *Kropa*. The preamble of applicant's claims distinguishes the presently claimed invention by defining an *orally administered agent* containing a drug that is released in the digestive tract, which area of technology is unique and presents significantly more difficulties compared to, for example, the flexible, hydrophilic gel film that is applied to the skin or mucous membrane, such as proposed by Roreger. Therefore, applicant respectfully submits that teachings that are not concerned with an *orally administered agent* containing a drug that is released in the digestive tract, such

as those of Roreger, could not possibly motivate one of ordinary skill in the art to the presently claimed orally administered agent.

Furthermore, the teachings of Roreger propose that in the case of buccal or sublingual application of the gel film, the active substance can be released to the system circulation via the mucous membrane of the mouth. In this case, the gel film has a back layer that prevents removal of larger amounts of active substance from the gel film via the saliva and prevents large amounts of active substance from being absorbed gastrointestinally after choking (column 10, lines 54-60 of Roreger). Accordingly, it would be readily apparent to those persons skilled in the art that the flexible, hydrophilic gel film proposed by Roreger is not an orally administered agent containing, *inter alia*, a drug that is released in the digestive tract, as required in present claims 1 and 13.

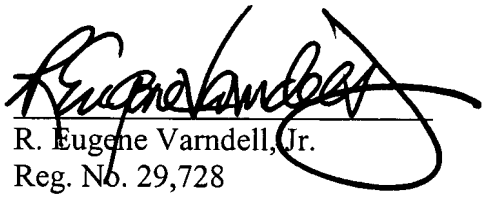
Furthermore, given the discussion of choking at column 10, lines 54-60 of Roreger, applicant respectfully submits that it is impossible for these teachings to contemplate or suggest that *the agent is swallowed without getting stuck in a trachea*, as required in present claim 13. In particular, applicant respectfully submits that it is impossible and improper to modify the teachings of Roreger to include an *agent being swallowed without getting stuck in a trachea*, when the teachings of Roreger propose an advantage to the gel film therein choking the user. The courts have repeatedly held that references cannot properly be modified or combined, if the effect would destroy the invention on which reference is based. *In re Randol and Redford*, 165 USPQ 586 (CCPA 1970); *Ex parte Thompson*, 184 USPQ 558 (PTO Bd. Pat Apps. & Interf. 1974); *Ex parte Hartman*, 186 USPQ 336 ((PTO Bd. Pat Apps. & Interf. 1976).

At least for the foregoing reasons, applicant respectfully submits that the inventions defined in claims 1-10 and 13 are patently distinguishable from the teachings of Roreger. Therefore, applicant respectfully requests that the examiner reconsider and withdraw this rejection and formally allow claims 1-10 and 13, together with withdrawn claims 10 and 11.

While it is believed that the present response is a complete and proper response to the Official action mailed August 1, 2007, should the examiner have any comments or questions, it is respectfully requested that the undersigned be telephoned at the below listed number to resolve any outstanding issues.

In the event this paper is not timely filed, applicant hereby petitions for an appropriate extension of time. The fee therefor, as well as any other fees which become due, may be charged to our deposit account No. 50-1147.

Respectfully submitted,



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